FEB - 1 2001

K003840

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Manufacturing Site:	I. C. Medical, Incorporated 2002 West Quail Avenue Phoenix, Arizona 85027-2610
Contact:	Craig Harshman (623) 780-0700 (phone) (623) 780-0887 (fax) icmedcial@sprintmail.com (e-mail)
Summary Date:	November 28, 2000
Device Trade Name:	I. C. Medical, Inc. Crystal Vision 250D for either 120 VAC or 240 VAC
Device Common Name:	Smoke Evacuator System
Device Classification Name:	APPARATUS, EXHAUST, SURGICAL Air-handling apparatus for a surgical operating room. Regulation Number: 21 CFR 878.5070
Establishment Registration Number:	2027757
Device Class:	Class II
Classification Advisory Panel:	General and Plastic Surgery
Predicate Device:	The predicate devices are the I. C. Medical, Inc. Crystal Vision and Accessories Model 360 (K932230) and the Stackhouse AirSafe Electrosurgical Smoke Evacuator (K912651)
Device Description:	The I. C. Medical, Inc. Crystal Vision 250D is an apparatus used for removing smoke plume and aerosol from surgical sites.
Intended Use:	The I. C. Medical, Inc. Smoke Evacuator Crystal Vision 250D is intended to be used to evacuate the smoke and particles created by electrosurgery, laser surgery, argon beam coagulators, LEEP devices, power tool or other aerosol producing surgical procedure devices. The device is intended to be used in all locations where smoke, particles, and/or aerosols are produce. Location for use includes Operating Rooms, Trauma, Emergency Departments, and C-Section Rooms.
Substantial Equivalence:	The I. C. Medical, Inc. Smoke Evacuator Crystal Vision 250D is substantially equivalent to I. C. Medical, Inc. Crystal Vision and Accessories Model 360 (K932230) and the Stackhouse AirSafe Electrosurgical Smoke Evacuator (K912651) in that: • intended use is same • performance attributes are similar
Summary of Testing and Validation:	The material used in the I. C. Medical, Inc. Crystal Vision 250D were tested in accordance to industry recognized test standards and was validated for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Craig Harshman
Director of QA, Regulatory Affairs & Operations
I.C. Medical, Incorporated
2002 West Quail Avenue
Phoenix, Arizona 85027

Re: K003840
Trade Name: Crystal Vision # 250D Smoke Evacuator System with Accessories
Regulatory Class: II
Product Code: FYD
Dated: November 28, 2000
Received: December 12, 2000

Dear Mr. Harshman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication of Use

510 (k) Number (if known): K003840

Device Name: I. C. Medical, inc. I. C. Medical, Inc. Crystal Vision 250D for either 120 VAC or 240 VAC

Indication For Use:

The I. C. Medical, ~~Inc. Smoke Evacuator Crystal~~ Vision 250D is intended to be used to evacuate the smoke and particles created by electrosurgery, laser surgery, argon beam coagulators, LEEP devices, power tool or other aerosol producing surgical procedure devices. The device is intended to be used in all locations where smoke, particles, and/or aerosols are produce. Location for use includes Operating Rooms, Trauma, Emergency Departments, and C-Section Rooms.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number_____

Prescription Use _____ OR Over-The Counter Use X
(Per 21 CFR 801.109

(Optional Format 1-2-96)

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(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003840